REMARKS

The Present Invention

The present invention is directed to a hydrophilic polymer bead comprising a three dimensional open-cell lattice having a highly porous structure that provides in each bead an intrusion volume of at least 3 ml/g. Applicants have developed a process to create these highly porous beads by first forming an emulsion comprising an aqueous phase, an organic phase (e.g., cyclohexane) and a hydrophilic polymer material. This emulsion is then injected or otherwise dispersed in a "cryogenic" fluid medium such as liquid nitrogen for a period of time sufficient to freeze the emulsion and thus form frozen emulsion droplets. The frozen emulsion droplets are then isolated and then freeze dried to remove both the aqueous and organic phases so as to form the highly porous beads.

Applicants have shown that beads so formed have two types of pores, one arising from the removal of ice crystals from the aqueous phase and the other from the removal of the organic phase. Applicants have further found that it is the removal of both aqueous and organic phases by for example freeze drying that leads to the high porosity of the inventive bead.

Claim Rejections - 35 USC § 102

Claims 1-4 and 6-21 were rejected under 35 U.S.C. §102(b) as being anticipated by Deluca '745 (US patent 5,160,745). Applicants' respectfully submit that Deluca '745 does not qualify as a 102(b) reference because it does not disclose in a single reference all the elements recited in applicants' claims.

Deluca '745 discloses porous microspheres (0.5 μm to 500 μm) having a three dimensional gel network (column 4, line 5). The microspheres are made by

first dissolving a biodegradable polymer and a monomer in aqueous solution. This solution is emulsified in a non-aqueous solvent and then polymerized at a temperature near 0° C. After polymerization the resulting microspheres are washed in water, isolated and then freeze dried (column 8, line 48 to column 9, line 6 and Example 5, columns 11-12).

Deluca '745 does not disclose the step of freezing the entire emulsion by injecting it into a cryofluid to form a frozen particle which after removal of both the aqueous and organic phases produces the highly porous polymer bead. Thus, the Deluca '745 microsphere contain only one type of pore namely those which are formed by freeze-drying a polymer particle containing only water.

In contrast, applicants' beads which have a diameter of the order 0.2 to 5 mm are formed by freezing an emulsion containing both an aqueous and non-aqueous phase and subsequently freeze-drying this frozen emulsion to remove both phase. This is a fundamental difference from the process disclosed by Deluca '745 and as shown in applicants' examples 1 and 2 Vs comparative example 3 gives rise to an entirely different internal pore structure. It is the presence of the large pores which are "left behind" after the internal phase medium in the frozen emulsion has been removed that is responsible for the very high porosity and low density of the beads of the invention as expressed by an intrusion volume of at least 3 ml/g.

Thus, Deluca '745 does not disclose beads formed by applicants' emulsion-freezing process, and consequently does not disclose beads having the three dimensional open-cell lattice that provides the highly porous structure (two types of pores) characterized by an intrusion volume of at least 3 ml/g. Since Deluca '745 does not disclose all the key elements of applicants' invention as recited in independent claims 1 and 12 it does not anticipate applicants' invention.

In light of the above remarks, applicants' respectfully request that the 102(b) rejection over Deluca et al (US patent 5,160,745) be reconsidered and withdrawn.

Claims 1-4 and 6-21 were rejected under 35 U.S.C. §102(e) as being anticipated by Holmes '159 (US patent 6,693,159). Applicants' respectfully submit that Holmes '159 does not qualify as a 102(e) reference because it does not disclose in a single reference all the elements recited in applicants' claims.

Holmes '159 is directed to manufacture of highly crosslinked polymer porous "monoliths". The process disclosed by Holmes involves dissolving selected monomers in supercritical CO_2, polymerization of these monomers and finally evaporating the CO_2. Supercritical CO_2 has a solubility product of 20-22 $MPa^{1/2}$ and is similar in solvent properties to heptane, i.e., sCO_2 is not a hydrogen bonding solvent like water (solubility parameter of water is 47 $MPa^{1/2}$). Therefore, the monomers employed by Holmes '159 are not hydrophilic and consequently the polymer is not a hydrophilic polymer.

Holmes '159 does not disclose the step of freezing the entire emulsion by injecting it into or contacting it with a cryofluid to form a frozen particle which after removal of both the aqueous and organic phases produces the highly porous polymer bead. Thus, Holmes '159 discloses polymeric monoliths containing pores formed by removal of CO_2 which Holmes '159 discloses acts as both a solvent and a porogen. Consequently, the Holmes '159 monoliths have intrusion volumes in the 0.5-1 ml/g range as seen in the second column of Table 2 for examples 1-8.

In contrast to Holmes '159, applicants beads are comprised of a hydrophilic polymer, have two types of pores which arise from the unique process involving freezing of emulsions in a cryofluid followed by freeze drying to remove both the aqueous and nonaqueous phases comprising the emulsion and

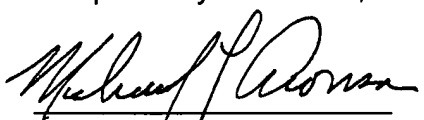
posses intrusion volumes at least about 3ml/g (at least 3 times higher than the highest values disclosed by Holmes '159).

Since Holmes '159 does not disclose all the above key elements of applicants' invention as recited in independent claims 1 and 12 it does not anticipate applicants' invention.

In light of the above remarks, applicants' respectfully request that the 102(e) rejection over Holmes et al (US patent 6,693,159) be reconsidered and withdrawn and that the application be allowed to issue.

If a telephone conversation would be of assistance in advancing prosecution of the subject application, applicants' undersigned agent invites the Examiner to telephone him at the number provided.

Respectfully submitted,



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